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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,181	07/26/2001	Felix Theeuwes	DURE-023	9651

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/917,181	THEEUWES ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-13,19-22,24,25 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24,25 and 32* is/are allowed.

6)☒ Claim(s) *1,2,4,6-9,11-13,19-22,29-31 and 33* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response of August 17, 2007 stating that it appeared that prosecution has been re-opened but that there was no Supervisory Primary Examiner's signature as is required.

It is noted that the present Office action includes the Supervisory Primary Examiner's signature as prosecution is re-opened following Applicants' appeal brief filed December 20, 2006. A response to Applicants' arguments in the brief is provided further below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6-9, 11-13, 20, 22, 29, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolinsky et al. 5,087,244, in light of Elsberry et al., 6,551,290.

Wolinksy discloses an elongate body (10) comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a lumen in the elongate body, said lumen extending between the proximal and distal ends;

and a diffuser element (16) operatively associated with the elongate body so as to define a diffusion space (i.e., space within element 16), wherein the elongate body distal end outlet is disposed in and in fluid communication with the diffusion space, and wherein the diffusion space is drug-permeable and water-permeable to provide for dilution of a drug in the diffusion space. The device is capable of providing for dilution of a drug because of the holes in the balloon (16). It is noted that dilution is a recitation of the intended use of the claimed invention. Recitation of an intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art structure is capable of performing the intended use. That is, the device is capable of providing for dilution of drugs within the device, since the balloon is capable of containing drugs and is porous such that it allows fluid to enter the device for dilution of the drug. The porosity of the balloon is considered to be due to holes (29) or alternatively, the material polyethylene, which is porous as evidenced by Elsberry et al., in column 7, lines 9-27, disclosing polyethylene to be a porous material with diffuser capability. That is, in the alternative, balloon 16 is considered to be a diffuser element as claimed because it is made of the same material as that disclosed by Applicants, namely, polyethylene (see col. 3, lines 47-49 in Wolinsky et al., and page 17, in paragraph 0073 of Applicants' specification). Thus, since the material of Wolinsky et al. is the same as the material disclosed by Applicants as having the capability of providing for dilution of a drug, the Wolinksy balloon 16 is considered to have the capabilities

recited by Applicants. This capability, i.e., permeability which allows for dilution, is also evidenced by Elsberry et al., in column 7, lines 9-27, disclosing polyethylene to be a porous material with diffuser capability.

As to claim 2, the diffuser element (16) comprises a semipermeable membrane, a microporous membrane. (The element 16 has minute holes (29) that is considered semipermeable since it allows through medicine or fluid but not substances that are larger than the size of the pores. It is noted that Applicants do not recite what drugs and thus any drugs can be considered.)

As to claim 4, the distal outlet of the elongate body is defined by an exit orifice (20) of a drug delivery device and the diffuser element (16) is considered a cap in which the exit orifice is disposed since element (16) is at the distal end of elongate body.

As to claim 6, the diffusion space is defined by an outer wall of the elongate body (10) and an inner wall of the diffuser element (16), (see lumen at and near 20, Figure 2.)

As to claim 7, said diffuser element (16) envelops at least a portion of said elongate body (10), see Figure 2.

As to claim 8, the diffuser element is microporous, (minute holes 29, column 4, lines 1-2.) Alternatively, the porosity of the balloon is considered to be due to the material polyethylene, which is porous as evidenced by Elsberry et al., in column 7, lines 9-27, disclosing polyethylene to be a porous material with diffuser capability.

As to claim 9, the diffuser element is considered a dense membrane, (see column 5, lines 22-24, and lines 49-51.)

As to claim 11, said diffuser element distal end extends distally beyond the elongate body distal end, see Figure 2.

As to claim 12, the diffuser element distal is ring-shaped element, see Figure 2.

As to claim 13, the diffuser element is selectively permeable to water (column 4, lines 3-5.)

As to claim 20, the device is operably attached to a drug delivery reservoir, (column 5, lines 25-26.)

As to claim 22, the balloon (16) is capable of delivering in microliter or submicroliter quantities per day since it can contain drugs and is porous which allows for drugs to be delivered.

As to claim 29, the diffuser element comprises a polymeric film, (column 3, lines 47-49.)

As to claim 31, the elongate body is drug-impermeable, and the diffuser element is substantially impermeable to drug and selectively permeable to water. (Applicant has not recited exactly what drug or what biological fluids or components in biological fluids in the claims. The Wolinsky device is capable of allowing fluids through (see col. 4, lines 21-22), while preventing passage of a drug larger than the openings.

As to claim 33, the diffuser element is substantially impermeable to biological fluids or components of biological fluids (i.e., biological fluids or components of biological fluids that are larger than the size of the openings in the device). The Office notes that Applicant has not recited exactly what biological fluids or components of biological fluids.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 24 and 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky et al., 5,087,244, in light of Elsberry et al., 6,551,290.

Wolinsky discloses the invention substantially as claimed (see above).

Wolinsky discloses that the "aggregate flow area defined by the holes 29 is selected so that under the general range of inflation pressures expected, the liquid flow through the holes will be very low, weeping in nature, and will not exceed a predetermined maximum flow rate in atmosphere. Although the foregoing configuration of holes is believed to be satisfactory for a wide range, and possibly most, if not all, medications or drugs to be delivered, it is possible that certain medications or drubs [believed by Examiner to be a misspelling for 'drugs'] may have viscosity and flow characteristics as might require modifications to the holes" (column 4, lines 19-29.)

As to claims 19 and 24, Applicants claim that the elongate body lumen is adapted for delivery of agent at a low volume rate. Applicants disclose in the specification on paragraph 0054:

"The term "low volume rate delivery" as used herein is generally meant to refer to delivery of a liquid or semisolid drug at a volume rate of from about 0.01 .mu.l per day to about 200 .mu.l per day, usually about 0.04 .mu.l per day to about 20 .mu.l per day, more usually about 0.1 .mu.l per day or about 1.0 .mu.l per day."

Wolinksy disclose on column 4, lines 19-24 that the aggregate flow area defined by the holes 29 is selected so that under the general range of inflation pressures expected, the liquid flow through the holes will be very low, weeping in nature, and will not exceed a predetermined maximum flow rate in atmosphere. The Wolinksy device is intended to deliver medicine and thus a low volume rate delivery as claimed and described by Applicants is within a workable range and thus is within the skills of the ordinary artisan.

As to claim 30, Wolinsky however does not teach that the diffuser element has a Diffusion Coefficient value in the range between 4.1 x 10-6 and 3.3 x 10-5 ug/cm/sec. However, it would have been obvious to form the diffuser element in which the holes' size and spacing is selected such that it has the specific Diffusion Coefficient as claimed, since Wolinsky teaches that medications may have viscosity and flow characteristics that might require modifications to the holes.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky et al., 5,087,244, in light of Elsberry et al., 6,551,290, and in view of Aoki et al., 6,113,915.

Wolinsky discloses the invention substantially as claimed (see above). Wolinsky teaches a catheter for delivery drugs to a body member having a lumen (column 2, lines 49-53.) However, Wolinksky does not disclose that the catheter contains Baclofen.

Aoki teaches use of a small catheter to deliver baclofen to treat spasticity since the intrathecal space is generally wide enough to accommodate a small catheter (column 2, lines 41-45.) It would have been obvious to use the Wolinsky catheter to deliver baclofen to treat spasticity since the intrathecal space is generally wide enough to accommodate a small catheter, as taught by Aoki.

Allowable Subject Matter

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 24, 25 and 32 are allowed.

Response to Arguments

Applicants' arguments in the appeal brief filed December 20, 2006 have been fully considered. However, the application is not in condition for allowance for the reasons as follow.

Applicants argue that the balloon of Wolinsky et al. is not a diffuser element because 1) it does not provide for diffusion of a drug from inside the balloon to the

outside, 2) it does not provide for dilution of drug in a diffusion space of the device, and 3) it does not provide for a diffusion element that comprises a material that permits diffusion through it. Applicants argue that the structural characteristics of the Wolinsky balloon are different, and that Wolinsky et al. disclose that the device delivers drug from the balloon upon application of pressure to force the drug out of the openings of the balloon. Applicants assert that the Wolinsky et al. balloon does not provide for passive movement of drug by diffusion.

These arguments are not persuasive for the following reasons. The grounds for rejection have been amended for clarification. As indicated above, the device is capable of providing for dilution of a drug because of the holes in the balloon (16). It is noted that dilution is a recitation of the intended use of the claimed invention. Recitation of an intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art structure is capable of performing the intended use. That is, the device is capable of providing for dilution of drugs within the device, since the balloon is capable of containing drugs and is porous such that it allows fluid to enter the device for dilution of the drug. The porosity of the balloon is considered to be due to holes (29) or alternatively, the material polyethylene, which is porous as evidenced by Elsberry et al., in column 7, lines 9-27, disclosing polyethylene to be a porous material with diffuser capability. That is, in the alternative, balloon 16 is considered to be a diffuser element as claimed because it is made of the same material as that disclosed

by Applicants, namely, polyethylene (see col. 3, lines 47-49 in Wolinsky et al., and page 17, in paragraph 0073 of Applicants' specification). Thus, since the material of Wolinsky et al. is the same as the material disclosed by Applicants as having the capability of providing for dilution of a drug, the Wolinksy et al. balloon 16 is considered to have the capabilities recited by Applicants. This capability, i.e., permeability which allows for dilution, is also evidenced by Elsberry et al., in column 7, lines 9-27, disclosing polyethylene to be a porous material with diffuser capability.

As to Applicants' argument regarding the deflation of the balloon, this argument is moot as this disclosure is no longer relied upon in the grounds for rejection.

Applicants also argue that the 25 micron holes in the Wolinsky et al. balloon does not render it capable of diffusion because the material is not permeable. This is not persuasive because the claims do not recite to what materials the diffuser element is permeable or impermeable, and thus the claims encompass any materials to which the Wolinksy et al. balloon is permeable or impermeable. Moreover, as discussed above, the Wolinsky et al. balloon is comprised of the same material as that disclosed by Applicants as having the permeability and impermeablity recited.

Applicants' arguments regarding an ion-exchange membrane as well as the method claims are persuasive. The claims directed to these subject matter are now indicated as allowable.

As to Applicants' argument that Wolinsky et al. do not teach a cap, this is not persuasive since the balloon (16) covers an orifice and thus is considered a cap.

As to Applicants' argument that the Wolinsky et al. balloon is cylindrical and not ring-shaped, this is not persuasive because something that is cylindrical and hollow is considered ring-shaped, and vice versa.

As to Applicants' argument that the Wolinksy et al. device is not capable of the intended use regarding delivery of an agent at a low volume rate (referring to claim 19), this is not persuasive because Applicants do not define what is considered to be "low", ("[G]enerally meant" is not a definition, but an example), and thus the Wolinsky et al. device is deemed to be capable of delivering at a low volume rate.

As to the argument that the Wolinksy et al. device is not capable of delivering drug in microliter or submicroliter quantities per day, this is not persuasive because this language relates to intended use, and the balloon (16) is capable of delivering drugs in microliter or submicroliter quantities per day since it can contain drugs and is porous which allows for drugs to be delivered.

Applicants also state that Wolinsky et al. only disclose that the balloons have holes of 25 microns in diameter, and such holes will permit any molecule, ion, or particle less than 25 microns to pass through, including very large particles such as red and white blood cells. Applicants assert that since it is hard to imagine that there are many (if any) relevant particles in blood that are larger than white blood cells, the balloon of Wolinksy et al. must not be substantially impermeable to biological fluids or components of biological fluids, as recited in claim 30. This is not persuasive for at least the reason that Applicants do not recite what components and what biological fluids, and thus the

claim encompasses impermeability to any matter that may be found in biological fluids, including foreign matter, bacteria, clumps of biological matter,....etc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Y. Lam
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